



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0563]

Odalys Fernandez: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Odalys Fernandez from providing services in any capacity to a person that has an approved or pending drug product application for a period of 6 years. FDA bases this order on a finding that Ms. Fernandez was convicted of five felony counts under Federal law for conduct involving health care fraud, and one count of conspiracy to commit health care fraud, and that this pattern of conduct is sufficient to find that there is reason to believe she may violate requirements under the FD&C Act relating to drug products. Ms. Fernandez was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Ms. Fernandez failed to request a hearing. Ms. Fernandez's failure to request a hearing constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr. (ELEM-4144), Rockville, MD 20857, 301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(ii)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(ii)(I)) permits debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of any criminal offense, and FDA finds, on the basis of the conviction and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe the individual may violate requirements under the FD&C Act relating to drug products.

On November 9, 2012, the U.S. District Court for the Southern District of Florida entered judgment against Ms. Fernandez after a jury found her guilty of five counts of health care fraud in violation of 18 U.S.C. 1347, and one count of conspiracy to commit health care fraud in violation of 18 U.S.C. 1349.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for these convictions is as follows: Ms. Fernandez was a registered nurse working for Ideal Home Health Inc. (Ideal), which was a business in Miami-Dade County, FL. Ideal purportedly provided skilled nursing services to Medicare beneficiaries who required home health services. As a registered nurse in the home health field, it was Ms.

Fernandez's duty to provide skilled nursing services to patients and maintain proper documentation of all treatments provided to patients.

From on or about August 17, 2007, through on or about March 19, 2009, Ms. Fernandez conspired with others to defraud Medicare.

Ms. Fernandez and her coconspirators submitted, and caused the submission of, false and fraudulent claims to Medicare, and concealed the submission of these false and fraudulent claims.

Ms. Fernandez and her coconspirators falsified and caused Medicare beneficiaries to falsify weekly visit/time record sheets, and falsified skilled nursing progress notes representing that she had administered insulin injections and provided other medical services to Medicare beneficiaries. She caused Ideal to submit false and fraudulent claims to Medicare for home health benefits by falsely representing that she had provided these health services. As a result of these fraudulent claims, she caused Medicare to make payments to Ideal of approximately \$82,040. Ms. Fernandez engaged in this criminal conduct repeatedly over a period of approximately 19 months.

As a result of her convictions, on September 8, 2014, FDA sent Ms. Fernandez a notice by certified mail proposing to debar her for 6 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on the finding, under section 306(b)(2)(B)(ii)(I) of the FD&C Act, that Ms. Fernandez was convicted of felonies under Federal law for conduct involving health care fraud and conspiracy to commit health care fraud, and the Agency found, on the basis of the conviction and other information, that Ms. Fernandez had demonstrated a pattern of conduct sufficient to find that there is reason to believe she may violate requirements under the FD&C Act relating to drug products. This

conclusion was based on the fact that Ms. Fernandez had legal and professional obligations to ensure that she submitted accurate medical claims for services she provided. Instead, Ms. Fernandez submitted, and caused the submission of, false weekly visit/time records and false daily blood sugar/insulin log sheets. She engaged in this conduct repeatedly over a period of almost 2 years. Her convictions indicate that she knowingly and willfully disregarded her legal and professional obligations to keep accurate medical records and to submit accurate claims for the services she provided. Having considered the conduct that forms the basis of her conviction and the fact that this conduct occurred in the course of her profession and showed a disregard for the obligations of her profession and the law, FDA found that Ms. Fernandez has demonstrated a pattern of conduct sufficient to find that there is reason to believe that, if she were to provide services to a person that has an approved or pending drug application, she may violate requirements under the FD&C Act relating to drug products. The proposal offered Ms. Fernandez an opportunity to request a hearing, providing her with 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. The proposal was received on September 12, 2014. Ms. Fernandez failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and has waived any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(b)(2)(B)(ii)(I) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Odalys Fernandez has been convicted of five counts of a felony and one count of conspiracy to commit a felony under Federal law for

conduct involving health care fraud and, on the basis of the conviction and other information, finds that Ms. Fernandez has demonstrated a pattern of conduct sufficient to find that there is reason to believe she may violate requirements under the FD&C Act relating to drug products.

Based on the factors under section 306(c)(2)(A)(iii) of the FD&C Act, FDA finds that each offense be accorded a debarment period of 3 years. In the case of a person debarred for multiple offenses, FDA shall determine whether the periods of debarment shall run concurrently or consecutively (section 306(c)(2)(A)). FDA has concluded that the 3-year periods of debarment for the five counts of health care fraud shall run concurrently. The 3-year period of debarment for the conspiracy conviction shall run consecutively to the periods of debarment for health care fraud convictions, resulting in a total debarment period of 6 years.

As a result of the foregoing findings, Odalys Fernandez is debarred for 6 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see DATES)(see sections 201(dd), 306(c)(1)(B), and 306(c)(2)(A)(ii) of the FD&C Act, (21 U.S.C. 321(dd), 335a(c)(1)(B), and 335a(c)(2)(A)(ii)). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Ms. Fernandez in any capacity during her debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Ms. Fernandez provides services in any capacity to a person with an approved or pending drug product application during her period of debarment she will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new

drug applications submitted by or with the assistance of Odalys Fernandez during her period of debarment (section 306(c)(1)(A) of the FD&C Act).

Any application by Ms. Fernandez for termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2014-N-0563 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 24, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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